

Two Phase Thermally Deformable Biocompatible Absorbable  
Polymer Matrix for Use in Medical Devices

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Field of the Invention

10 The general field to which the invention relates to is  
devices made of absorbable polymer matrices.  
Specifically, absorbable polyester matrices for use in a  
thermally deformable plating system for the fixation of  
bone and cartilage, especially hard tissue of the  
cranium.

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Background of the Invention

Synthetic absorbable biocompatible polymers are well  
known in the art. Such polymers are typically used to  
20 manufacture medical devices, which are implanted in body  
tissue and absorb over time. Synthetic absorbable  
biocompatible polymers include homopolymers, copolymers  
(random, block, segmented and graft) of monomers such as  
glycolic acid, glycolide (d, l, meso and mixtures  
25 thereof), lactic acid, lactide,  $\epsilon$ -caprolactone,  
trimethylene carbonate and p-dioxanone. Numerous U.S.  
Patents describe these polymers including 5,431,679;  
5,403,347; 5,314,989; 5,431,679; 5,403,347; and  
5,502,159.

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There is a constant need in this art for new polymer compositions having improved physical properties when molded or extruded into medical devices and further having excellent in vivo properties. For  
5 example, it is known that copolymers of lactide and glycolide have good in vivo properties (U.S. Patent 5,569,250). These materials are also generally known in the art to be single phase, amorphous or semi-crystalline copolymers with melting points exceeding  
10 100°C, and no low melting or immiscible component.

Heat deforming of absorbable devices, such as plates, has also been described in U.S. Patent 5,569,250. However, one drawback of such devices is their lack of a  
15 visual cue to aid the surgeon in knowing the precise time that they can begin deforming the device. This is critical to the device, because premature bending or otherwise manipulating it before it has relaxed (i.e., heated above its T<sub>g</sub> or T<sub>m</sub>) can cause stresses to form in  
20 the part, weakening it, especially in clinical situations.

Unfortunately, U.S. Patent 5,569,250 does not recognize that absorbable plates, rods and pins, for example,  
25 could be manufactured from a polymeric material that provides a visual cue to a surgeon during surgery to assist him/her in appropriately applying the device to the surgical site.

30 Therefore, what is needed in this art is a novel device that provides a visual cue during its application (i.e.,

deformation during heating) to indicate when it can be safely manipulated or shaped.

The surgical devices of the present invention provide a visual cue to surgeons indicating when the surgical device may be contoured or shaped.

### Summary of the Invention

10 We have discovered an absorbable polymeric matrix that provides a visual cue when heated that the absorbable polymeric matrix may be deformed without significantly reducing the strength (due to internal stress concentration) of a device made from the polymeric  
15 matrix. These polymeric matrices are especially well suited for use in implantable surgical devices such as plates, pins, rods and the like that need to be shaped during medical procedures to accommodate the patient. The method of shaping a surgical article containing  
20 these absorbable polymeric matrices comprises heating the surgical article until a visual cue is provided by the absorbable polymeric matrix that the portion of the surgical article made from the absorbable polymeric matrix may be safely shaped, then shaping that portion  
25 of the surgical article to the desired final shape and allowing the surgical article to cool.

The foregoing and other features and advantages of the invention will become more apparent from the following  
30 description and accompanying examples.